

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF ILLINOIS**

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<b>IN RE PRADAXA</b>	)	<b>MDL No. 2385</b>
<b>(DABIGATRAN ETEXILATE)</b>	)	<b>3:12-md-02385-DRH-SCW</b>
<b>PRODUCTS LIABILITY</b>	)	<b>Judge David R. Herndon</b>
<b>LITIGATION</b>	)	

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**This Document Relates to:**

**ALL CASES**

**CASE MANAGEMENT ORDER NUMBER 58**  
**Regarding RE-LY Discovery Issue**

**HERNDON, Chief Judge:**

Pending is an issue raised with the Court in letter form by the Plaintiff's Steering Committee ("PSC") yesterday, February 21, 2014 and responded to by defendants in like form today. It involves a re-examination of, what is now well known in this litigation, the RE-LY study. The Court will not review the details of this re-examination because the parties do not dispute the plaintiffs are entitled to discover that which they seek, and accordingly, such a review is not necessary.

The dispute is over timing. The PSC wants the material essentially in real time. It seeks the how, what, where, when and who as it happens throughout this re-examination process. The defendants prefer to wait until after the re-examination process is over. If, however, production is delayed until the re-examination process is over, depositions of the defendants' researchers (one of whom was mid-deposition when the PSC wrote the Court) will be complete (some have already been deposed and others have yet to be examined under oath).

Stepping back for one moment to refresh recollections that don't need refreshing, this litigation has from the beginning been in fast forward. First, the undersigned sets that tone in multi-district litigation as a matter of course. Secondly, this particular litigation, by its nature demanded a rapid response by the third branch of government to the issues at hand. The complaints which were on file, with both sides suggesting hundreds more to come (now there are well in excess of 2,000), made very serious allegations for which the medical community, the defendants, the first branch of government and the nation as a whole needed answers sooner rather than later. Plus, the plaintiff population is an aged one and would not be appropriately served by a lingering litigation timeline. Consequently, an aggressive pretrial schedule and time to first trial was adopted and the first trial deadline has been strictly adhered to. However, many things have to go right in order for such an aggressive schedule to work well and many things have not gone right, as any observer of this litigation knows from the orders this Court has issued.

The result of an aggressive schedule and more things having gone wrong than right throughout the pretrial proceedings is that motions are made by letter and through email. Responses are handled the same. Deadlines that are anticipated cannot be the usual 30 days from when asked and requests for extension are routinely consented to. Litigation of this type is far from the normal litigation. It is complex litigation by definition. The problems are complex by expectation, made more complex by certain actions and inactions. The Court,

however, will not in this order recollect all the actions and inactions; that is not the point of this order. The point is if one were to take a snapshot of this dispute in isolation: a letter on February 20 asking for extraordinary relief to take place by 5:00 PM the next day; the response the very next morning by someone on the other side of the globe; one might say this is all very unreasonable on many levels.

The plaintiffs argue this pace is necessitated by the nature of the litigation, particularly in light of previous discovery abuses. They contend they are entitled to depose key researchers involved in the re-examination process. Specifically, they need to learn about the re-examination process, the researcher's role in the re-examination, and the findings produced as a result of the re-examination. Further, the plaintiffs assert they need to depose the involved researchers now - without having to go back to them for another shot at those questions. They see no burden at all in requiring the defendants to produce these materials at this time.

Defendants argue, tacitly that it should be more like a normal discovery process. Ask for it and we have 30 days to produce it. They recognize, however, how this litigation has had to operate. They further argue though that more importantly, the re-examination must be allowed to finish and then they will produce all of that to which plaintiffs are entitled. They cite as authority, *Dow Chemical Co. v. Allen*, 672 F.2d 1262 (7th Cir. 1982). They also remind the Court of a similar order on the subject of a paper which defendants wanted to discover in the YAZ litigation.

Unfortunately, this litigation must move rapidly and while it is frustrating to all participants at times it is important to many people, even outside of the direct participants. While the authority cited by the defendants is not directly on point, the Seventh Circuit case does provide some guidance. The YAZ order was clearly different in that it dealt more with the concept of academic freedom. As the concept in *Allen* discussed, there is a huge problem with providing the materials the PSC seeks in real time (on a rolling basis as they termed it). Giving the plaintiffs a virtual place at the table as defendants conduct this re-examination could very well, if not almost guarantee, a stifling of the purpose of the re-examination. If part of the conversation becomes put a copy here for us and a copy over there for the PSC, an inherent conflict arises in the process that may well be counterproductive.

Accordingly, the Court **ORDERS** as follows: Once the re-examination is complete, defendants shall produce the documentation associated with it within 10 days. Should the plaintiffs need to re-depose any witnesses, they shall be allowed to do so. **FURTHER**, the defendants' request for production of material allegedly in the possession of the PSC relating to additional missed bleeding

events for patients in the RE-LY clinical trial is **DENIED**. The production of such material has already been addressed by the Court in CMO 51 (Doc. 368).

**SO ORDERED:**

 Digitally signed by  
David R. Herndon  
Date: 2014.02.21  
14:42:41 -06'00'

**Chief Judge**  
**United States District Court**

**Date: February 21, 2014**